REMARKS

Claims 1-6 and 8-14 are pending. Claims 8-13 have been withdrawn. Claim 1 has been amended to further defined Applicants' invention and is in independent form. Favorable reconsideration and allowance of the subject application are respectfully requested in view of the following comments.

Rejections Under 35 USC § 103

Claims 1-6 and 14 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,486,436 ("Sunshine et al."), U.S. Patent No. 4,943,565 ("Tencza et al."), Remington's Pharmaceutical Sciences p. 1837 ("Remington"), U.S. Patent No. 6,602,520 ("Schroeder et al.") and WO 01/87264 ("Jain et al.). Applicants respectfully traverse these rejections, in view of the comments set forth below.

Claim 1 is directed to a solid pharmaceutical dosage form that includes among its noteworthy features, caffeine, wherein the caffeine is in the form of uncoated ungranulated particles having a granular morphology and an average particle size of about 70 to 600 microns, and wherein at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

Applicants have previously noted (*see* Applicants' response dated August 27, 2010) superior dissolution rates found when uncoated ungranulated particles of caffeine having a granular morphology and an average particle size of about 70 to 600 microns are included in a solid pharmaceutical dosage form.

Applicants maintain that the proposed combination of Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences, and Schroeder et al., do not disclose or suggest the inclusion of uncoated ungranulated particles of caffeine having a granular morphology and an average particle size of about 70 to 600 microns.

Thus, it is respectfully submitted that if one skilled in the art were to combine Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences, and Schroeder et al. as proposed, the resulting solid pharmaceutical dosage form may possibly exhibit a dissolution rate where at least 75% of the caffeine-acetaminophen tablet dissolves in under 45 minutes.

The claimed solid pharmaceutical dosage form recited in Claim 1, on the other hand, exhibits a greater dissolution rate in a shorter period of time. This is due to the inclusion

of uncoated ungranulated caffeine particles having a granular morphology and an average particle size of about 70 to 600 microns. Applicants have observed that at least 86% of the caffeine dissolves within 5 minutes, when measured by USP, Type II Apparatus (Paddles) set at 50 rpm.

As such, Claim 1 is patentable over the proposed combination of Sunshine et al., Tencza et al., Remington's Pharmaceutical Sciences (p. 1837), and Schroeder et al.

The remaining claims, i.e., Claims 2-6 and 14, directly or indirectly depend from Claim 1. For at least the same reasons discussed above for Claim 1, Claims 2-6 and 14 are patentable over the proposed combination of Sunshine et al., Tencza et al., Remington, and Schroeder et al.

Conclusion

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and allowance of the claims in the present application.

Applicants' undersigned attorney may be reached in our office by telephone at (732) 524-1767. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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